

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/IL2005/000442

International filing date (day/month/year)
28.04.2005

Priority date (day/month/year)
29.04.2004

International Patent Classification (IPC) or both national classification and IPC
A61N1/36, A61B5/11, A61B5/0488, A61H1/02

Applicant
REABILITY INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IL2005/000442

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IL2005/000442

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 33

because:

- ☒ the said international application, or the said claims Nos. 33 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 33
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

Re Item III.

No search has been carried out (Rule 39.1(iv) PCT) for claim 33, since it relates to a method for treatment of the human or animal body by therapy. Indeed, claim 33 pertains to the delivery of a therapeutic neuromuscular stimulation signal to the human body. Consequently, no opinion will be formulated with respect to the subject-matter of this claim (Article 34(4)(a)(i) PCT).

Re Item V.

1. Reference is made to the following documents:
D1 : WO 02/092164 A (FONDATION SUISSE POUR LES CYBERTHESES;
BRODARD, ROLAND; CLAVEL, REYMON) 21 November 2002
D2 : US 5 466 213 A (HOGAN ET AL) 14 November 1995
D3 : US 4 499 900 A (PETROFSKY ET AL) 19 February 1985
D4 : US 4 724 842 A (CHARTERS ET AL) 16 February 1988
2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.
- 2.1 Document D1 (see in particular figs. 1-4) discloses (the references in parentheses applying to this document) an apparatus for muscle activation comprising:
 - at least one electrode (37, 38) adapted to deliver a neuromuscular stimulation signal to a body portion;
 - at least one controller (31) adapted to provide a NMES signal comprising a sequence of stimulation signals to said at least one electrode; and
 - a mechanical motion element (2, 3, 4, 6, 7, 8, 20, 21, 22) coupled to at least one of said body portion and a mirror body portion,
 - wherein said mechanical motion element is operatively coupled to said at least one controller (see fig. 4) and wherein said at least one controller controls said NMES signal in conjunction with said mechanical motion element (p. 12, 2nd paragraph and p. 21, second and third paragraphs).

- 2.2 D2 (see in particular fig. 14) also anticipates the subject-matter of claim 1, since it discloses an apparatus for muscle activation comprising:
- at least one electrode (E1, E2) adapted to deliver a neuromuscular stimulation signal to a body portion;
 - at least one controller (AB, 32) adapted to provide a NMES signal comprising a sequence of stimulation signals to said at least one electrode; and
 - a mechanical motion element (10) coupled to at least one of said body portion and a mirror body portion,
 - wherein said mechanical motion element is operatively coupled to said at least one controller and wherein said at least one controller controls said NMES signal in conjunction with said mechanical motion element (col. 6, l. 54-59).
- 2.3 Further, the subject-matter of claim 1 lacks novelty in view of D3 (see abstract and figs. 1-2) and D4 (see abstract and figs. 1-2).
3. Dependent claims 2-32 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, the reasons being as follows:
- 3.1 D1 anticipates the subject-matter of following claims (Article 33 (2) PCT):
- Claims 1-5: in D1, the mechanical motion element moves, guides and measures motion of the body portion (first leg) and the mirror body portion (second leg), which motion is in response to said NMES sequence.
 - Claim 6: the controller of D1 is programmable, so a programmer is implicitly disclosed in D1.
 - Claim 7: in D1, a closed loop feedback control for both the mechanical motion and the EMG controlled stimulation is effected: hence a sequence optimisation is also disclosed.
 - Claims 11-15: see D1, p. 21, second and third paragraphs.
 - Claim 17: see memory (39) of D1.
 - Claims 18-20: in D1, the operator can modify the stimulation sequence as desired (see p. 19, 4th paragraph - p. 20, 3rd paragraph).
 - Claim 22: force sensor (35) in D1.
 - Claim 28: in D1, one can choose from stimulation only, stimulation assisted

rehabilitation and "mechanical" rehabilitation only (see p. 21, last paragraph - p. 23, 3rd paragraph): therefore, the controller can act independently of the mechanical motion element.

- Claim 29: in D1, the electrodes are placed on the thighs and on the legs (see fig. 4), hence the NMES sequence is for application to at least two muscles.

- Claim 31: mechanical motion elements (2, 3, 4) and motors (20, 21, 22) of D1 represent a robotic actuator (see also p. 15, l. 2).

- 3.2 The features of claims 8-10, 21, 23-27, 30 and 32 represent slight constructional changes from the known devices which come within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Moreover, these features concern straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to improve the known devices. Consequently, the subject-matter of these claims lacks an inventive step (Article 33 (3) PCT).

Re Item VI.

Certain published documents

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 2004/050172	17.06.2004	03.12.2003	04.12.2003

This document could become relevant for novelty in further proceedings before the EPO.

Re Item VII.

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor are these documents identified therein.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/IL2005/000442

2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

FENSTER, Paul et al.
FENSTER & COMPANY
INTELLECTUAL PROPERTY LTD.
P.O. Box 10256
IL-49002 Petach Tikva
ISRAEL

NOTIFICATION OF RECEIPT OF DEMAND BY COMPETENT INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

(PCT Rules 59.3(e) and 61.1(b), first sentence
and Administrative Instructions, Section 601(a))

Date of mailing
(day/month/year)

21-03-2006

Applicant's or agent's file reference

414/04493

IMPORTANT NOTIFICATION

International application No.

PCT/IL2005/000442

International filing date (day/month/year)

28/04/2005

Priority date (day/month/year)

29/04/2004

Applicant

REABILITY INC. et al.

1. The applicant is hereby **notified** that this International Preliminary Examining Authority considers the following date as the date of receipt of the demand for international preliminary examination of the international application:

28/02/2006

2. This date of receipt is:

- ☒ the actual date of receipt of the demand by this Authority (Rule 61.1(b)).
☐ the actual date of receipt of the demand on behalf of this Authority (Rule 59.3(e)).
☐ the date on which this Authority has, in response to the invitation to correct defects in the demand (Form PCT/IPEA/404), received the required corrections.

3. ☒ **ATTENTION:** That date of receipt is **after** the expiration of 19 months from the priority date. Consequently, in respect of some Offices, the demand does not have the effect of postponing the entry into the national phase until 30 months from the priority date (or later in some Offices) (Article 39(1)) and the acts for entry into the national phase must therefore be performed within 20 months from the priority date (or later in some Offices). **However**, in respect of some other Offices, the time limit of 30 months (or later) may nevertheless apply. See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

- ☐ (If applicable) This notification confirms the information given by telephone, facsimile transmission or in person on:

4. Only where paragraph 3 applies, a copy of this notification has been sent to the International Bureau.

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